



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO. |
|----------------|-------------|----------------------|--------------------|------------------|
| 09 620,038 | 07/20/2000 | Udo Hoss | RDID 0050 US | 3787 |

7590 08/09/2002

Attn: Jill L. Woodburn
The Law Office of Jill L. Woodburn, L.L.C.
6633 Old Stonehouse Dr.
Newburgh, IN 47630

EXAMINER

GITOMER, RALPH J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1627 | 14 |

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|---------------------------|------------------|
| Application No. | Applicant(s) |
| 09/620,038 | Hoss et al. |
| Examiner Ralph Gitomer | Art Unit 1627 |



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on May 7, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 23-50 and 68-79 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 23-50 and 68-79 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

5

The amendment received 5/7/02 has been entered and claims 23-50, 68-79 are currently pending in this application. New claim 68 includes the limitation ~~in~~ alternating successive transport and dialysis intervals at different flow rates~~s~~.

The rejection under 35 USC 103 over Pfeiffer (6,091,976) is maintained.

10

Applicant's arguments filed 5/7/02 have been fully considered but they are not persuasive.

15

Applicants argue that Pfeiffer teaches setting an initial glucose concentration in the perfusion solution which is maintained unchanged during testing. The predetermined glucose baseline is set in other words. Whereas the presently claimed invention includes adjusting the starting content of glucose in the perfusate in accordance with a command variable corresponding with the glucose concentration of the body fluid.

20

It is the examiner's position that as presently claimed, this point of novelty feature is so vague as to not be possible to distinguish from Pfeiffer. Pfeiffer teaches in the abstract, continuously detected signals for monitoring tissue glucose concentrations. The predetermined concentration is set within the physiological range depending on the tissue glucose concentration as described in column 1 last paragraph. The function of the teaching of Pfeiffer and that presently claimed

25

appears identical. See the present specification page 2 last full paragraph.

5 The rejection under 35 USC 112, second paragraph, is maintained and includes claims 23-50, 68-79.

10 Claim 23 as amended still does not have a step which determines glucose concentration. Note there may be some confusion between content and concentration in the claims. The determining of the starting content of glucose in claims 25 and 26 remains indefinite.

15 Regarding new claims 68-79, in claim 68 ~~in~~ alternating successive transport and dialysis intervals ~~is~~ is not understood. Further, ~~measuring measurement signals~~ is unclear because no measurement signals have been obtained and what they might be measured for is not seen. And how can one adjust the starting content of glucose if one must first measure the glucose concentration? If the starting content of glucose is set according to a command of some sort, how can the momentary starting content of glucose be a measure of glucose content of 20 the body fluid? If a feedback is intended to adjust the starting glucose concentration, it is not found in the claims as presented. Claim 76 contains many values but how they are obtained is not found in the claims. There are many instances of lack of antecedent basis in the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5

10

15

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20

25

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (703) 308-4537. The fax phone number for this Art Unit is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business Center for more information.

5

10

Ralph Gitomer

Ralph Gitomer
Primary Examiner
Group 1627

PALPH GITOMER
PRIMARY EXAMINER
GROUP 1627